AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for preparing a conjugate vaccine in commercial volumes, the method comprising:

reacting a polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained;

reacting a protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained;

purifying said solution of hydrazine-activated protein under conditions standardized to process at least five liters of solution;

reacting the aldehyde-activated polysaccharide with the hydrazine-activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained; ~~and~~

neutralizing unreacted aldehyde groups with adipic acid dihydrazide; and

purifying the resulting solution under conditions standardized to process a volume of at least two liters,

whereby a conjugate vaccine capable of stimulating an immune response is obtained in commercial volumes.

2. (Original) The method according to claim 1, wherein the oxidizing agent comprises $NaIO_4$.

3. (Original) The method according to claim 1, wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged with a HEPES buffer.

4. (Original) The method according to claim 1, wherein the solution of the aldehyde-activated polysaccharide is buffer exchanged to a pH of from about 7 to about 8.

5. (Original) The method according to claim 1, wherein the solution of the hydrazine-activated protein is buffer exchanged with a Na_2CO_3 buffer.

6. (Original) The method according to claim 1, wherein the solution of the hydrazine-activated protein is buffer exchanged to a pH of from about 10.0 to about 11.0.

7. (Original) The method according to claim 6, wherein a pH of the solution of the hydrazine-activated protein is raised to from about 7.0 to about 11 before the solution of the hydrazine-activated protein is buffer exchanged to a pH of from about 10.0 to about 11.0.

8. (Original) The method according to claim 1, wherein the aldehyde-activated polysaccharide is reacted with the hydrazine-activated protein at a ratio of from about 1:1.6 to about 1:5.

9. (Currently Amended) The method according to claim 1, wherein said purifying the resulting solution comprises ~~further comprising~~ the step of diafiltrating the conjugate vaccine, whereby substantially all unreacted compounds and unconjugated polysaccharides are removed, yielding a purified conjugate vaccine.

10. (Original) The method according to claim 9, further comprising the step of concentrating the purified conjugate vaccine by tangential flow ultrafiltration, yielding a concentrated purified conjugate vaccine.

11. (Original) The method according to claim 10, further comprising the step of adding saccharose as a stabilizer to the concentrated purified conjugate vaccine, yielding a stabilized conjugate vaccine.

12. (Original) The method according to claim 10, further comprising the step of freeze drying the concentrated purified conjugate vaccine, yielding a dried conjugate vaccine.

13. (Original) The method according to claim 1, wherein the polysaccharide is selected from the group consisting of Meningococcal polysaccharides, Pneumococcus polysaccharides, Hemophilus influenzae type b polysaccharide, Vi polysaccharide of Salmonnella typhi, and group B Streptococcus polysaccharides.

14. (Original) The method according to claim 1, wherein the protein is selected from the group consisting of tetanus toxoid, diptheria toxoid, CRM_{197}, and meningococcal protein.

15. (Currently amended) A method for preparing a conjugate vaccine in commercial volumes, the method comprising:

reacting a polysaccharide with an oxidizing agent, whereby a solution of an aldehyde-activated polysaccharide is obtained;

buffer exchanging the solution of the aldehyde-activated polysaccharide to a pH of from about 7 to about 8;

reacting a protein with hydrazine dichloride at an acidic pH, whereby a solution of a hydrazine-activated protein is obtained;

raising a pH of the solution of the hydrazine-activated protein to from about 7.0 to about 11 and thereafter buffer exchanging the solution of the hydrazine-activated protein to a pH of from about 10.0 to about 11.0;

purifying said solution of hydrazine-activated protein under conditions standardized to process at least five liters of solution;

reacting the aldehyde-activated polysaccharide with the hydrazine-activated protein at a pH of from about 5 to about 7 in the presence of sodium cyanoborohydride, whereby a conjugate is obtained; and

neutralizing unreacted aldehyde groups with adipic acid dihydrazide, and purifying the resulting solution under conditions standardized to process a volume of at least two liters,

whereby a conjugate vaccine capable of stimulating an immune response is obtained in commercial volumes.

16. (Previously presented)The method according to claim 15, wherein the aldehyde-activated polysaccharide is reacted with the hydrazine-activated protein at a ratio of from about 1:1.6 to about 1:5.

17. (Currently amended) The method according to claim 15, wherein said purifying the resulting solution comprises ~~further comprising~~ the step of diafiltrating the conjugate vaccine, whereby substantially all unreacted compounds and unconjugated polysaccharides are removed, yielding a purified conjugate vaccine.

18. (Previously presented)The method according to claim 17, further comprising the step of concentrating the purified conjugate vaccine by tangential flow ultrafiltration, yielding a concentrated purified conjugate vaccine.

19. (Previously presented)The method according to claim 18, further comprising the step of adding saccharose as a stabilizer to the concentrated purified conjugate vaccine, yielding a stabilized conjugate vaccine.

20. (Previously presented)The method according to claim 15, wherein the polysaccharide is selected from the group consisting of Meningococcal polysaccharides, Pneumococcus polysaccharides, Hemophilus influenzae type b polysaccharide, Vi polysaccharide of Salmonnella typhi, and group B Streptococcus polysaccharides, and wherein the protein is

selected from the group consisting of tetanus toxoid, diptheria toxoid, CRM_{197}, and meningococcal protein.